

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GILEAD SCIENCES, INC.,

Plaintiff,

v.

APOTEX, INC., LUPIN LIMITED,
LAURUS LABS LIMITED, SHILPA
MEDICARE LIMITED, SUNSHINE LAKE
PHARMA CO., LTD., NATCO PHARMA
LIMITED, CIPLA LIMITED, MACLEODS
PHARMACEUTICALS LTD., HETERO
USA INC., HETERO LABS LIMITED
UNIT-V, AND HETERO LABS LIMITED,

Defendants.

C.A. No. 20-00189 (MN)

[PROPOSED] SCHEDULING ORDER

This ____ day of June, 2020, the Court having received a proposed scheduling order from the parties, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration; IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard. The parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) by **June 9, 2020**. The parties have reviewed the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at <http://www.ded.uscourts.gov> (see Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

(a) Per paragraph 3 of the Default Standard for Discovery, the parties shall serve Initial Discovery Disclosures by **July 2, 2020**.

(b) Per Paragraph 4(a) of the Default Standard for Discovery, Gilead shall identify the accused products and asserted patents and produce file histories by **July 2, 2020**.

(c) Per Paragraph 4(b) of the Default Standard for Discovery, Defendants shall produce their complete ANDAs and tenofovir DMFs on or before **June 19, 2020**.¹ [**Gilead's Proposal: Defendants shall produce product samples on or before July 30, 2020**²; **Defendants' Proposal: Defendants will individually confer with Gilead about production of product samples**].

(d) Per Paragraph 4(c) of the Default Standard for Discovery, Gilead shall serve its Initial Infringement Claim Chart by **September 10, 2020**.

¹ Defendants will produce DMFs to the extent they are within their possession, custody, or control. Any Defendant Group that does not produce the tenofovir DMF for one or more of its ANDA products shall, on this date, identify the entity that allegedly has possession, custody and control of the DMF and provide a written explanation why the Defendant Group cannot produce the DMF.

² Gilead proposes that each Defendant Group shall produce 50 unexpired tablets for each of its ANDA product(s). [**Plaintiff's Position: Gilead's proposal is in line with scheduling orders issued in this District that have ordered production of product samples, to the extent possible, at the same time or shortly after other core technical documents. (See, e.g., 1:19-cv-00734-RGA, Dkt. No. 20; 1:19-cv-02192-RGA, Dkt. No. 16.) Gilead's proposal also provides a date certain on which Gilead has information to confirm infringement, potentially conduct product testing, if needed, and seek any additional discovery. Gilead is willing to confer with individual Defendant Groups in good faith if the global pandemic warrants an extension, but believes the Scheduling Order should, in order to reduce potential motion practice, (1) require production of product samples, and (2) include a target date for that production; Defendants' Position: In view of the global pandemic, including an ongoing lockdown in India where many of the samples sought by Gilead are located, Defendants are unable to commit to a date certain for sample production at this time. Defendants do not intend to unreasonably delay sample production, assuming production of samples is deemed necessary and proportional, but believe the more appropriate course of action is for each Defendant to confer individually with Gilead regarding the availability and discoverability of unexpired samples and the timing for sample production**].

(e) Per Paragraph 4(d) of the Default Standard for Discovery, Defendants shall serve their Initial Invalidity Contentions and Accompanying Document Production by **November 5, 2020**.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **January 29, 2021**. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 7(g) and 8.

3. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court by **June 15, 2020**. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 7(g) below.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version

of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

5. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and any other document filed in support of any briefs (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

6. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

7. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules shall be strictly observed.

(a) Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **October 21, 2021**.

(b) Document Production. Document production shall be substantially complete by **May 7, 2021**.

(c) Requests for Admission. Gilead may serve up to 40 requests for admission on each Defendant Group.³ Defendants may serve up to 20 common requests for admission on Gilead. Additionally, each Defendant Group may serve up to 20 additional individual requests for admission on Gilead.

(d) There is no limit on the number of requests for admission the parties may serve to establish the authenticity of documents.

(e) Interrogatories.

³ Each of Apotex, Lupin, Hetero, Sunshine Lake, Cipla, Natco, Laurus, Shilpa, and Macleods are a separate Defendant Group.

i. Gilead may serve up to 15 common interrogatories on Defendants, to which each Defendant Group will respond separately. Additionally, Gilead may serve up to 10 additional individual interrogatories on each Defendant Group. Defendants may serve up to 15 common interrogatories on Gilead. Additionally, each Defendant Group may serve up to 10 additional individual interrogatories on Gilead. All limits on interrogatories shall include subparts according to Fed. R. Civ. P. 33.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(f) Depositions.

i. Limitation on Hours for Deposition Discovery. Gilead may take 35 hours of party, third party, and Rule 30(b)(6) deposition testimony per Defendant Group. Defendants may collectively take 100 hours of party, third party, and Rule 30(b)(6) testimony. All depositions shall be limited in accordance with Fed. R. Civ. P. 30 to 1 day of 7 hours per witness (14 hours if translator needed). No deposition shall count for less than 3 hours against the hours limit.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a

counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

(g) Disclosure of Expert Testimony.

i. Expert Reports. For the parties who have the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **December 16, 2021**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **February 10, 2022**. Objective indicia of non-obviousness, if any, will be addressed in the first instance in Gilead's rebuttal expert reports. Reply expert reports from the party or parties with the initial burden of proof are due on or before **March 10, 2022**. Defendants' reply expert reports will include any response to Gilead's expert disclosure regarding objective indicia of non-obviousness. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. All expert discovery shall be completed **May 5, 2022**.

ii. The parties agree that they will not permit expert declarations in connection with motions briefing except for case dispositive motions (if any are allowed by the Court per paragraph 13) and briefing in connection with claim construction.

iii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than **fourteen (14) days after the close of expert discovery**,

unless otherwise ordered by the Court. Briefing will be presented pursuant to the Court's Local Rules.

(h) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after a reasonable effort pursuant to Local Rule 7.1.1., that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Judicial Administrator to schedule an argument.

iii. On a date to be set by separate order, generally not less than four (4) days prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than three (3) days prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. The parties shall provide to the Court two (2) courtesy copies of its discovery letter and any other document filed in support of any letter (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

v. Should the Court find further briefing necessary upon conclusion of the conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the conference and will, in that event, cancel the conference.

(i) Service and Timing. The parties consent to service by email, in accordance with Fed. R. Civ. P. 5(b)(2)(E).

8. Motions to Amend / Motions to Strike.

(a) Any motion to amend (including a motion for leave to amend) a pleading or any motion to strike any pleading or other document shall be made pursuant to the discovery dispute procedure set forth in Paragraph 7(g) above.

(b) Any such motion shall attach the proposed amended pleading as well as a “redline” comparison to the prior pleading or attach the document to be stricken.

9. Technology Tutorials. Although technology tutorials are not required by the Court, they are appreciated and, if any party chooses to file such a tutorial, it shall be submitted on or before the date that the Joint Claim Construction Brief is filed.

10. Claim Construction Issue Identification. On **November 19, 2020**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction. On **December 3, 2020**, the parties shall exchange their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted on **December 17, 2020**. The parties’ Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party’s proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

11. Claim Construction Briefing. The Plaintiff shall serve, but not file, its opening brief, not to exceed 20 pages, on **January 21, 2021**. The Defendants shall serve, but not file, their answering brief, not to exceed 30 pages, on **February 25, 2021**.⁴ The Parties shall complete any expert claim construction discovery by **March 11, 2021**. The Plaintiff shall serve, but not file, its reply brief, not to exceed 20 pages, on **April 1, 2021**. The Defendants shall serve, but not file, their sur-reply brief, not to exceed 10 pages, on **April 15, 2021**. No later than **April 29, 2021**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

⁴ To clarify, any Defendant Groups that propose the same claim constructions shall collectively serve and file joint claim construction briefs for those claim terms. If any individual Defendant Group seeks construction of a term that other Defendant Groups do not, or has a need to assert a construction that is different from the other Defendant Groups, that Defendant Group may serve a brief, not to exceed five pages, in addition to the collective joint answering claim construction brief, and Plaintiff will then have the right to serve separate reply briefs to those individual briefs, each additional brief not to exceed five pages, and the Defendant Group may serve a sur-reply brief not to exceed three pages.

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

12. Hearing on Claim Construction. Beginning at _____ on **Court's convenience, week of May 24, 2021**, the Court will hear argument on claim construction. The parties need not include any general summaries of the law relating to claim construction in their presentations to the Court. The parties shall notify the Court, by joint letter submission, no later than the date on which their joint claim construction brief is filed: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

13. Case Dispositive Motions. Absent agreement between the parties, and prior approval from the Court, the Court will not hear case dispositive motions in ANDA cases.

14. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

15. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine*

request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

16. Pretrial Conference. On **August 9, 2022**, the Court will hold a pretrial conference in Court with counsel beginning at _____. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than **July 26, 2022**. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) double-sided courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents.

17. Trial. This matter is scheduled for a **6 day** bench trial beginning on **September 6, 2022**.

18. Post-Trial Briefing. The parties propose that the parties file opening post-trial motions on **October 13, 2022**, oppositions to post-trial motions on **November 10, 2022**, and replies to post-trial motions on **December 1, 2022**.

UNITED STATES DISTRICT JUDGE

Proposed Case Deadlines

EVENT	Parties' Joint Proposed Date	Gilead's Proposed Date	Defendants' Proposed Date
Parties to Serve Rule 26(a)(1) Initial Disclosures	June 9, 2020		
Parties to Submit Joint Proposed Protective Order	June 15, 2020		
Parties to Serve Initial Discovery Disclosures (Per Paragraph 3 of the Default Discovery Standard)	July 2, 2020		
Gilead's Identification of Accused Products and Asserted Patents and Production of File Histories (Per Paragraph 4a of the Default Discovery Standard)	July 2, 2020		
Defendants to Produce ANDAs and Tenofovir DMFs ⁵	June 19, 2020		
Defendants to Produce Product Samples ⁶		July 30, 2020	Defendants will individually confer with Gilead about production of product samples
Gilead's Initial Infringement Claim Chart (Per Paragraph 4c of the Default Discovery Standard)	September 10, 2020		
Defendants' Initial Invalidity Contentions and Accompanying Document Production (Per Paragraph 4d of the Default Discovery Standard)	November 5, 2020		

⁵ Defendants will produce DMFs to the extent they are within their possession, custody, or control. Any Defendant Group that does not produce the tenofovir DMF for one or more of its ANDA products shall, on this date, identify the entity that allegedly has possession, custody and control of the DMF and provide a written explanation why the Defendant Group cannot produce the DMF.

⁶ Gilead proposed that each Defendant Group produce 50 unexpired tablets for each of its ANDA product(s).

EVENT	Parties' Joint Proposed Date	Gilead's Proposed Date	Defendants' Proposed Date
Parties to Exchange List of Terms to be Construed	November 19, 2020		
Parties to Exchange Proposed Constructions	December 3, 2020		
Parties to File Final Joint Claim Construction Chart	December 17, 2020		
Gilead to Serve Opening Claim Construction Brief	January 21, 2021		
Last Day to Move to Join Parties or Amend Pleadings	January 29, 2021		
Defendants to Serve Responsive Claim Construction Brief	February 25, 2021		
Complete Expert Claim Construction Discovery (if any)	March 11, 2021		
Gilead to Serve Reply Claim Construction Brief	April 1, 2021		
Defendants to Serve Sur-Reply Claim Construction Brief	April 15, 2021		
Parties to Submit Joint Claim Construction Brief	April 29, 2021		
Parties to Submit Claim Construction Tutorials	April 29, 2021		
Claim Construction Hearing	Court's convenience, week of May 24, 2021		
Substantial Completion of Document Production	May 7, 2021		
Close of Fact Discovery	October 21, 2021		
Parties to Serve Opening Expert Reports	December 16, 2021		
Parties to Serve Rebuttal Expert Reports	February 10, 2022		

EVENT	Parties' Joint Proposed Date	Gilead's Proposed Date	Defendants' Proposed Date
Parties to Serve Reply Expert Reports	March 10, 2022		
Close of Expert Discovery	May 5, 2022		
Last Day to File <i>Daubert</i> Motions	May 19, 2022		
Rebuttal <i>Daubert</i> briefs	June 9, 2022		
Reply <i>Daubert</i> briefs	June 23, 2022		
Parties to File Joint Proposed Pretrial Order	July 26, 2022		
Pretrial Conference	August 9, 2022		
Trial	September 6-13, 2022		
Opening Post-Trial Motions	October 13, 2022		
Oppositions to Post-Trial Motions	November 10, 2022		
Reply to Post-Trial Motions	December 1, 2022		
Expiration of "30 Month" Stay	May 5, 2023		